UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF POLLUTION PREVENTION AND TOXICS

REGULATION OF A NEW CHEMICAL SUBSTANCE

PENDING DEVELOPMENT OF INFORMATION

In the matter of:	)	Premanufacture Notice Numbers:
	)	
	)	
	)	
	)	
	)	
_____	)	_____ _____
	)	
	)	
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	)	
	)	

Consent Order and Determinations Supporting Consent Order

Commented [1]:
The PAG Consortium understands seeks to confirm that the Agency intends that each Consortium Member who also is a PMN submitter for a PAG substance that has been considered to be within "scope" will receive its own Consent Order modeled after this template.

The Consent Order issued to a PMN submitter will apply only to that company's PMNs that are under review.

If a Consortium Member/PMN submitter has multiple PMNs currently under review that fall within scope, each PMN substance will be addressed (listed) in the same Consent Order.

If a signatory submits a subsequent PMN after signing its initial Consent Order, the signed Order will be modified to add the new PMN substance(s) to the originally-listed chemicals.

Moreover, we understand the conditions of use in each PMN will be reflected in the draft Orders the PMN submitters receive and in any Modifications that will be made to refer to and incorporate subsequent PMNs submitted that fall within scope. We anticipate that accommodations may need to be made in modifications to individual Consent Orders when subsequent PMNs are submitted to the extent those PMNs describe conditions of use which differ from those currently under review.

Further, substances that were subject to LVEs that were "granted" prior to the formation of the PAG Consortium and for which PMNs were not required to be submitted are not expected to be affected by the model Consent Order.

[PAGE * MERGEFORMAT]

TABLE OF CONTENTS

PREAMBLE

I. INTRODUCTION

The attached Consent Order is entered into voluntarily by the Environmental Protection Agency ("EPA" or "the Agency") and _____ ("the Company"), regarding premanufacture notices ("PMNs") P-_____ for the chemical substances _____ ("the PMN substances"). The PMN substances fit within the scope of the "PAG Category" definition set forth in Attachment A.

The attached Consent Order is issued under the authority of § 5(e) of the Toxic Substances Control Act ("TSCA") (15 U.S.C. § 2604(e)). The Company submitted the PMNs to EPA pursuant to § 5(a)(1)(B) of TSCA and 40 C.F.R. pt. 720.

Under § 15 of TSCA, it is unlawful for any person to fail or refuse to comply with any provision of TSCA, any order issued under TSCA, or any consent order entered into under TSCA. Violators may be subject to various penalties and to both criminal and civil liability pursuant to § 16 of TSCA, and to specific enforcement and seizure pursuant to § 17 of TSCA. In addition, chemical substances subject to an order issued under § 5 of TSCA, such as this one, are subject to the § 12(b) export notice requirement.

II. SUMMARY OF TERMS OF THE CONSENT ORDER

The attached Consent Order requires the Company to:

(a) refrain from manufacturing any of the PMN substances beyond the time limits specified in the Testing section of the attached Consent Order unless the Company or the Semiconductor Photoacid Generator (PAG) Consortium (hereinafter referred to as "the Consortium") submits to

Commented [2]: The PAG Consortium recommends omitting this term given there are a variety of time limits articulated in the various Tiers and Steps in the draft Consent Order.

EPA the results of certain testing described in the Testing section of the attached Consent Order. The time limits may be extended upon request with written approval from EPA;

(b) not modify the processing or use of the PMN substances in any way that generates vapor, dust, mist or aerosol in a non-enclosed process;

(c) use the PMN substances only as described in the PMNs for [semiconductor photolithography formulations] manufacture;

~~(d) refrain from manufacturing (excluding import) the PMN substances in the United States (i.e., import only);~~

~~(e) import only in solution;~~

(f) not exceed an annual importation volume of XX kg/yr for any use;

(g) distribute the PMN substances only to a person who agrees to follow the same restrictions (except the testing requirements) and to not further distribute the PMN substances; and

(h) maintain certain records.

III. CONTENTS OF PMNs

By signing the Consent Order, the Company represents that it has carefully reviewed this document and agrees that all information herein that is claimed as confidential by the Company is correctly identified within brackets, that any information that is not bracketed is not claimed as confidential, and that the Company has previously submitted any information so marked to EPA under a claim of confidentiality in accordance with the requirements of TSCA and applicable regulations. To make this document available for public viewing, EPA will remove only the information contained within the brackets.

Commented [3]: The PAG Consortium members understand that to the extent a PMN describes a condition of use during manufacture or processing that requires the use of PPE to mitigate inhalation concerns, this would be incorporated into the draft Consent Order drafted by EPA for that submitter's situation. The PAG Consortium members request that EPA insert as few unnecessary conditions as possible in the Consent Orders. Unnecessary terms that impose limitations that are not related to specific risk concerns imposes unnecessary restrictions that may generate revocation and modification requests at later dates.

Commented [4]: PAG Consortium members understand the Consent Orders ultimately to be provided to each PMN submitter to review will differ from the "model" Order because it will have been adjusted to reflect the conditions of use described in the submitter's PMN.

Commented [5]: For certain PMN submitters, this use description may be confidential with respect to third parties who are not PAG Consortium members. The Consortium understands EPA reviewers will adjust whether this needs to be [bracketed] as CBI in individual Consent Orders. In such circumstances, the PAG Consortium understands this term would be adjusted accordingly.

Moreover, the Consortium understands that to the extent EPA is identifying inhalation concerns for one or more PAG substances, the Agency does not intend to add to the testing Tiers described in this Consent Order any additional testing (such as inhalation studies) that are not contemplated in this draft Order.

Commented [6]: PAG Consortium members understand that if an individual PMN describes the Company's intent to manufacture in the US, or to import its PMN substance(s) in a solid form, or to embark on other conditions of use that are not already described in their PMNs, then they can/should raise this in the course of negotiating the terms of the specific draft Consent Order when received from EPA.

Commented [7]: The PAG Consortium expects this term to be adjusted depending on the conditions of use that are described in the submitter's PMN including with respect to physical state, etc.).

Moreover, we understand the conditions of use in each PMN will be reflected in the draft Orders the PMN submitters receive and in any Modifications that will be made to refer to and incorporate subsequent PMNs submitted that fall within scope.

Commented [8]:

Commented [9]: PAG Consortium members are not certain how EPA will determine what volume to insert in this provision. Presumably, the volume entered in this section will be consistent with the annual production volume estimate provided by the PMN submitter. Nevertheless, the Consortium requests clarification from EPA on this point.

Confidential Business Information Claims (Bracketed in the Preamble and the Consent Order):

Chemical Identity:

Specific:

Generic:

Use:

Specific:

Generic:

Maximum 12-Month Production Volume:

Test Data Submitted with PMN:

IV. EPA'S ASSESSMENT OF EXPOSURE AND RISK

The following is EPA's assessment regarding the probable human and environmental toxicity, and human exposure and environmental release of the PMN substances, based on the information currently available to the Agency.

Persistent, Bioaccumulative, and Toxic Concern:

EPA identified human health and environmental concerns because the PMN substances potentially may be persistent, bioaccumulative, and toxic (PBT) chemicals, based on physical/chemical properties of the PMN substances, as described in the New Chemicals Program's PBT category (64 FR 60194, November 4, 1999)(FRL-6097-7). EPA estimates that the PMN substances potentially may persist in the environment for more than two months and estimates a potential bioaccumulation factor of greater than or equal to 1,000.

Human Health Effects Summary:

EPA estimated the human health hazard of this chemical substance based on its estimated physical/chemical properties, and by comparing it to structurally analogous chemical substances for which there is information on human health hazard. Absorption is expected to be nil through the skin and poor through the lungs and GI tract based on physical/chemical properties. EPA identified photosensitization as a potential hazard based on photoreactivity, eye corrosion, irritation, acute toxicity, liver toxicity and neurotoxicity as hazards based on analogue data and reproductive (developmental) toxicity based on positive mutagenicity and the perfluoro anion analogue. For photoacid generators with polymeric anions with a molecular weight over 10,000 grams/mol, there is concern for lung overload by insoluble polymers.

Commented [10]: The Consortium Members expect and understand that this paragraph and the Hazard Communications provisions in the Ordre language will be adjusted to reflect the specific conditions of use and the Agency's concerns that are pertinent to the PMN substances under review.

Commented [11]: The Consortium members note that this sentence suggests there should be no need elsewhere in the model Order (e.g., in the Hazard Communication provisions) for EPA to include a requirement to provide dermal protection equipment and to avoid physical forms of the substance other than liquid.

Commented [12]: The Consortium members have not previously seen this paragraph. We ask the Agency to confirm that the passage will be tailored to express those concerns specific to the PMN substance or to be advised whether this is a description of EPA's concerns for all members of the "category".

Commented [13]: Similarly, the PAG Consortium had not been apprised of this concern previously in the context of PAG substances. If this is a "categorical" concern, the Consortium members wish to confirm that the statement of this concern in the model Order will not prompt the addition of studies not listed already in the tiered testing program already set forth in the model Order.

Environmental Effects Summary:

Environmental hazard is relevant to whether a new chemical substance is likely to present unreasonable risk because the significance of the risk is dependent upon both the hazard (or toxicity) of the chemical substance and the extent of exposure to the substance. EPA was unable to estimate the environmental hazard of this new chemical substance. Acute and chronic toxicity values estimated for fish, aquatic invertebrates, and algae are unknown due to insufficient information.

Risk to Workers:

Commented [14]: To our knowledge, the Consortium members who are PMN submitters have not been provided copies of the specific Engineering Report, Exposure Assessment, or an integrated Risk Assessment for their PMN substances. The Members who are PMN submitters would like to have access to these documents for purposes of review and to better inform themselves in the context of making future LVE and PMN submissions.

This/These new chemical substance(s) are subject to the terms set forth in this Consent Order, which includes measures that minimize exposure. Exposures for workers are estimated in the Engineering Report(s) for this/these case(s); they are not reported here because risks were not quantified due to insufficient information on hazard.

Risks to General Population:[]

This/These new chemical substance(s) are subject to the terms set forth in this Consent Order, which includes measures that minimize exposures. Exposures for the general population are estimated in the Exposure Report(s) for this/these case(s); they are not reported here because risks were not quantified due to insufficient information on hazard.

Risk to Consumers: []

Risks to consumers were not evaluated because consumer uses were not identified as conditions of use.

V. EPA'S DETERMINATION

Based on the foregoing:

(a) EPA is unable to determine whether the PMN substances will present an unreasonable risk to health or the environment. Information available to EPA indicates that there is a potential for human and environmental exposure to the PMN substances and that the PMN substances may be toxic to aquatic life and organisms and may cause [] in humans under the conditions of use. Therefore, pursuant to §§ 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I) of TSCA, EPA determines that

Commented [15]: The Consortium members understand and seek to confirm that the missing entries will be tailored for their PMN substance and the conditions of use described in their particular PMNs.

uncontrolled manufacture, processing, distribution in commerce, use, or disposal of the PMN substances may present an unreasonable risk of injury to health or the environment and that the limitations imposed by the Consent Order are necessary to protect against such risk.

VI. INFORMATION REQUIRED OR POTENTIALLY USEFUL TO EVALUATE HUMAN HEALTH AND ENVIRONMENTAL EFFECTS

Triggered Testing. The attached Consent Order prohibits the Company from manufacturing the PMN substances unless the Company or the Photoacid Generator Industry Consortium (hereinafter referred to as "the Consortium") submits the information described in accordance with the conditions and time periods specified in the Testing section of the attached Consent Order.

NOTE: Any request by EPA for the triggered testing described in the attached Consent Order was made based on EPA's consideration of available screening-level data, if any, as well as other information available on appropriate testing for the PMN substances. Further, any such testing request on the part of EPA that includes testing on vertebrates was made after consideration of available toxicity information, computational toxicology and bioinformatics, and high-throughput screening methods and predictive models. The triggered testing requirements specified in the Testing section reflect a tiered screening and testing process under which the results of lower-tiered testing, will inform a risk-based decision concerning whether additional tests are necessary. Such determinations with regard to the substances to be designated for testing and the studies to be

performed will be made only after the Agency has completed its review of the previously submitted data and tiered studies and reported its analyses to the PMN submitter and PAG Consortium representatives in the course of the agreed-upon "meet and confer" sessions referenced in Section (d)(1) and (d)(2) below.

CONSENT ORDER

I. SCOPE OF APPLICABILITY AND EXEMPTIONS

(a) Scope. The requirements of this Consent Order apply to all commercial manufacturing (including importing), processing, distribution in commerce, use and disposal of the chemical substances _____ (P-__-____)("the PMN substances") in the United States by _____ ("the Company"), except to the extent that those activities are exempted by paragraph (b).

(b) Exemptions. Manufacturing, processing, distribution in commerce, use and disposal of the PMN substances is exempt from the requirements of this Consent Order (except the requirements in the Recordkeeping and Successor Liability Upon Transfer Of Consent Order sections) only to the extent that (1) these activities are conducted in full compliance with all applicable requirements of the following exemptions, and (2) such compliance is documented by appropriate recordkeeping as required in the Recordkeeping section of this Consent Order.

Commented [16]: The PAG Consortium notes that this draft does not include the various exemptions ordinarily specified in other standard TSCA 5(e) Consent Orders, and which appear in the PMN regulations. By way of example, these have included exemptions pertaining to byproducts as codifed at § 720.30(g) and substances manufactured without a separate commercial intent as codified at § 720.30(h) as well as the exemption for imported articles. The Consortium requests those terms should be inserted. See edits below which are terms that appear in EPA's standard 5(e) "boiler plate" for Consent Orders. [HYPERLINK "https://www.epa.gov/sites/production/files/2016-09/documents/co_all_purpose_preamble_and_consent_order_combined_9-1-2016_clean.pdf"].

(1) Export. Until the Company begins commercial manufacture of the PMN substances for use in the United States, the requirements of this Consent Order do not apply to manufacture, processing or distribution in commerce of the PMN substances solely for export in accordance with TSCA §§12(a) and 12(b), 40 C.F.R. § 720.3(s) and 40 C.F.R. pt. 707. However, once the Company begins to manufacture, process, or distribute in commerce the PMN substances for use in the United States, no further activity by the Company involving the PMN substances is exempt as "solely for export" even if some amount of the PMN substances is later exported. At that point, the requirements of this Consent Order apply to all activities associated with the PMN substances while in the territory of the United States. Prior to leaving U.S. territory, even those quantities or batches of the PMN substances that are destined for export are subject to terms of the Consent Order, and count towards any production limit test triggers in the Testing section of this Consent Order.

(2) Research & Development ("R&D"). The requirements of this Consent Order do not apply to manufacturing, processing, distribution in commerce, use and disposal of the PMN substances in small quantities solely for research and development in accordance with TSCA §5(h)(3), 40 C.F.R. § 720.3(cc), and 40 C.F.R. § 720.36. The requirements of this Consent Order also do not apply to manufacturing, processing, distribution in commerce, use and disposal of the PMN substances when manufactured solely for non-commercial research and development as defined at 40 C.F.R. § 720.30(c).

(4) Byproducts. The requirements of this Order do not apply to the PMN substances

when it is produced, without separate commercial intent, only as a "byproduct" as defined at 40 CFR 720.3(d) and in compliance with 40 CFR 720.30(g).

(5) No Separate Commercial Purpose. The requirements of this Order do not apply to the PMN substances when manufactured, pursuant to any of the exemptions in 40 CFR 720.30(h), with no commercial purpose separate from the substance, mixture, or article of which it is a part.

(6) Imported Articles. The requirements of this Order do not apply to the PMN substances when imported as part of an "article" as defined at 40 CFR 720.3(c) and in compliance with 40 CFR 720.22(b)(1).

(6) Completely Reacted (Cured). The requirements of this Order do not apply to quantities of the PMN substance after they have been completely reacted or adhered (during photolithographic processes) onto a semiconductor wafer surface or similar manufactured article used in the production of semiconductor technologies.

(7) De Minimis Concentrations. The Hazard Communications provisions of this Order do not apply to quantities of the PMN substance that are (1) present in the work area only as a mixture and (2) at a concentration not to exceed 1.0 percent by weight or volume (0.1 percent by weight or volume if the PMN substance is identified as a potential carcinogen in the Hazard Communication Program section of this Order). This exemption is not available if the Company has reason to believe that, during intended activities, the PMN substance in the mixture may be reconcentrated above the 1.0 or 0.1 percent level, whichever applies.

(c) Automatic Sunset. If the Company has obtained for the PMN substances a Test Market Exemption ("TME") under TSCA §5(h)(1) and 40 C.F.R. § 720.38 or a Low Volume Exemption ("LVE") or Low Release and Exposure Exemption ("LoREX") under TSCA §5(h)(4) and 40 C.F.R. § 723.50(c)(1) and (2) respectively, the Company must cease manufacture and processing under these exemptions within 10 business days after the effective date of this Consent Order.

II. TERMS OF MANUFACTURE, PROCESSING, DISTRIBUTION IN COMMERCE, USE, AND DISPOSAL PENDING SUBMISSION AND EVALUATION OF INFORMATION

PROHIBITION

The Company is prohibited from manufacturing (which under TSCA includes importing), processing, distributing in commerce, using, or disposing of the PMN substances in the United States, for any nonexempt commercial purpose, pending the development of information necessary for a reasoned evaluation of the human health and environmental effects of the PMN substances, and the completion of EPA's review of, and regulatory action based on, that information, except in accordance with the conditions described in this Consent Order.

TESTING

(a) Section 8(e) Reporting. Reports of information on the PMN substances which reasonably support the conclusion that the PMN substances present a substantial risk of injury to health or the environment and which are required to be reported under § 8(e) of TSCA must reference the appropriate PMN identification numbers for the PMN substances and contain a statement that the PMN substances are subject to this Consent Order. Additional information regarding § 8(e) reporting requirements can be found at *https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/reporting-tsca-chemical-substantial-risk-notice.*

(b) Notice of Study Scheduling. The Company or the Consortium (acting on behalf of the Company) will notify, in writing, the EPA Monitoring Assistance and Media Programs Division, Office of Enforcement and Compliance Assurance (OECA), U.S. Environmental Protection Agency, of the information identified below within 20 business days of scheduling any study required to be performed pursuant to this Consent Order. Studies undertaken prior to the effective date of this Consent Order are not subject to this notification requirement. Notice will include:

(1) The study name and date when the study is scheduled to commence;

(2) The name and address of the laboratory which will conduct the study;

(3) The name and telephone number of a person at the Company, Consortium or the laboratory whom EPA may contact regarding the study; and,

(4) A statement that the PMN substances are "PAG Consortium Chemical Substances"

The written notice should be submitted to EPA/OECA as follows:

Postal Mail Address

U.S. Environmental Protection Agency

GLP Section Chief – Pesticides, Water and Toxics Branch

Monitoring Assistance and Media Programs Division (2227A)

Office of Enforcement and Compliance Assurance

1200 Pennsylvania Avenue, N.W.

Washington, DC 20460

Courier Delivery Address

U.S. Environmental Protection Agency

GLP Section Chief – Pesticides, Water and Toxics Branch

Monitoring Assistance and Media Programs Division (2227A)

Office of Enforcement and Compliance Assurance

Room 7117B

1200 Pennsylvania Avenue, N.W.

Washington, DC 20004

A copy of the written notice submitted to EPA/OECA must also be submitted concurrently as a support document for the PMN, using the procedures set out in 40 C.F.R. § 720.40.

(c) Good Laboratory Practice Standards and Test Protocols. Each study performed to address the risks identified in this Consent Order must be conducted according to TSCA Good Laboratory Practice Standards at 40 C.F.R. pt. 792 and using methodologies generally accepted in the relevant scientific community at the time the study is initiated. Before starting to conduct any study outlined below in Section (d)(2), the Company or the Consortium (acting on behalf of the Company) must submit written test protocols to EPA for review. Such protocol will be submitted to the designated EPA contact person for the Consortium in EPA's New Chemicals Management Branch who will coordinate the timely EPA review of the protocol with the appropriate EPA personnel. EPA will respond to the Consortium's designee or the Company within 4 weeks of receiving the written protocols. EPA review of a test protocol does not mean pre-acceptance of test results.

(d) Triggered Testing Requirements. The Company is prohibited from manufacturing (which includes importing) the PMN substances beyond the limits specified in the Consent Order unless the Company or the Consortium (acting on behalf of the Company) conducts the following studies, as outlined below in Section (d)(2) and as directed by EPA, on the following chemical substances that EPA considers to be representative of many of the photoacid generators previously submitted as new chemical notifications to the TSCA New Chemicals Program (hereinafter referred to collectively as the "test substances"):

- Iodonium, bis[4-(1,1-dimethyl)phenyl-, salt with 7,7-dimethyl-2-oxobicyclo[2.2.1] heptane-1-methanesulfonic acid(1:1) (CAS: 193345-23-2)
- Sulfonium, triphenyl-, salt with 2,2-difluoro-2-sulfoethyl tricyclo[3.3.1.13,7]decane-1-carboxylate (1:1) (CAS: 1048642-06-3)
- Sulfonium, tris[4-(1,1-dimethylethyl)phenyl]-, 1,1,2,2,3,3,4,4,4-nonafluoro-1-butanesulfonate (1:1) (CAS: 241806-75-7)
- Thiophenium, 1-[4-(1,1-dimethylethyl)phenyl]tetrahydro-, salt with 1,1,2,2,3,3,4,4,4-nonafluoro-1- butanesulfonic acid (1:1) (CAS: 900188-13-8)
- Sulfonium, (4-hydroxyphenyl)diphenyl-, salt with trifluoromethanesulfonic acid (1:1) (CAS: 141801-36-7)

Commented [17]: This edit corrects an error in the CAS number and nomenclature to align with the correct name and CAS number for this representative PAG previously agreed to among the parties. The Consortium may need to correct previously submitted study reports to ensure alignment on this issue.

The results of this testing will be used by EPA to assess whether the PAG Category or a subset of compounds in the PAG category present or may present an unreasonable risk of injury to human health or the environment.

(d)(1) Acknowledgement of Information Previously Submitted or to be Voluntarily Submitted by the Company or Consortium. In accordance with Tier 1 of the Agency's "Test Strategies for PAGs for Pre-Notice Consultation Discussions" (Memo dated June 2, 2017), the Company, as a collaborating member of the Consortium, has submitted information and data to EPA in the form of a conceptual model and other information (e.g., mass-balance analyses) that identified potential routes of occupational exposure and environmental release pathways, as well as

Commented [18]: The PAG Consortium would like EPA to confirm that the model it will be using is the version submitted to EPA most recently and which was discussed in the context of our most recent face-to-face meeting. The Consortium will provide a copy of the most recent edition for Agency use.

subsequent pathways for potential exposure to the general population through drinking water. The information provided estimates of the quantities of chemical substances within the PAG Category that are currently distributed annually for use in the US in the semiconductor manufacturing sector, calculations which approximated the quantities of such substances to which workers might be exposed and environmental releases that might result, and the estimated concentration(s) of each relevant chemical substance in such pathways. The updated conceptual model provided in Attachment C is expected to inform Agency analyses, including estimates of human and environmental exposure and the calculation of risk. These factors also will be considered when the parties are conferring regarding the need for any additional testing pursuant to Section (d)(2).

The Company, on its own or as a member of the Consortium, may also generate and submit information or data to address certain information gaps. Such information and data are not required under the terms of this Consent Order or may have been commenced prior to the execution of the Order, and consequently are not considered to be subject to the GLP requirements at 40 CFR 792. Such information and data may include analytical methods development, small scale photodegradation studies of the test substances in solution, the results of "on-wafer" studies, "tight-ion pair" evaluations, and other analyses to inform identification of environmentally relevant degradation products and estimate potential quantities released.

(d)(2) Tiered Triggered Testing. The following information will be provided in accordance with the intervals and volumes identified in Tiers and Steps below. The testing below requires EPA to meet and confer with the Consortium between certain Tiers and Steps as outlined below. When determining the need for additional studies and the substances for which such studies would be undertaken, EPA will take into account information submitted by the Consortium and its individual members, structural alerts, the potential for exposure, feasibility of obtaining degradants and/or ions of concerns, and other factors as appropriate. When establishing and modifying deadlines for when testing results are to be submitted, EPA also will consider the number of substances to be tested, the complexity of the test methods, as well as the length of time such studies require when evaluating novel chemistries.

Tier 1 - Physicochemical Properties and Fate
The Company or Consortium (acting on behalf of the Company) will characterize the five representative test substance(s) to determine what may be released to the environment following abiotic degradation of the test substances by performing the testing listed below and analyzing and quantifying products from testing on the environmental fate of the test substances. Standard test methods or protocols for some of the tests listed below may need to be modified or additional methods developed for specific test substances. The Company or Consortium will conduct the following testing:
Step 1
The Company or Consortium will conduct the following tests on the five test substances: • Analyses to assess whether test substances behave as tight ion pairs in aqueous media. Such analyses may include conductivity measurements as well as spectroscopic (UV-Vis) measurements. • Analytical method(s) for identifying PAGs and their cation photodegradation products in both simple and complex matrices by modifying existing methods or develop new test procedures and protocols as necessary, incorporating available technology and most current science. • a modified OECD 316/OPPTS Test Guideline 835.2210: Direct Photolysis Rate in Water by Sunlight, and the rest of OPPTS Test Guideline 835.2210 if the chemical shows absorption in the UV/Visible spectrum. • small scale photodegradation studies of the test substances in solution to determine rate of PAG transformation and nature/concentration of cation photolysis products in accordance with Beaker Photolysis experiment. • OECD Guideline 112: Dissociation Constants in Water (Titration Method – Spectrophotometric Method – Conductometric Method).[1] Timing: The Company individually, or as a member of the Consortium, is prohibited from manufacturing (which includes importing) the PMN substances beyond 18 months after the Agency has approved all of the pertinent analytical methods and test protocols submitted by the Consortium, unless the Tier 1, Step 1 testing for the test substances has been completed and provided to EPA. The time limit may be extended upon request with written approval from EPA. After Tier 1, Step 1 tests have been completed and results provided to EPA, the parties will meet to confer with regard to EPA's evaluation of the results data and to consider which substances will be evaluated and which studies will be performed for purposes of Tier 1, Step 2. Such consultations will begin no later than 4 weeks following EPA's receipt of the

Commented [19]: Given the number of substances being examined, the lack of established analytical methods for identifying the presence of the representative substances in the pertinent media, the Consortium thinks it is reasonable for additional time for performing these studies to be provided. Moreover, the trigger should not commence running until the pertinent methods and protocol have been approved by EPA.

[1] EPA understands that this method is being used for tight ion pair studies referenced in paragraph (d)(2) above and, therefore, the results of the tight ion pair analyses are expected to satisfy this requirement.

final study report for tests completed under Step 1 of Tier 1 and will be completed no later than 6 weeks thereafter. Identification of substances for subsequent testing will be determined in accordance with paragraph (d)(2).

Step 2

EPA, after reviewing the data submitted and meeting with the Consortium, will identify in writing to the Company and the Consortium the test substances, ions, and/or degradants for which the following testing will be performed. Identification of substances for testing will be based on data needs in light of potential risk. The number of substances to be tested may be fewer than, but will not exceed, the number of substances tested in the preceding Step.2 Such testing may include one or all of the following studies:

- OECD Test Guideline 111: Hydrolysis as a Function of pH
- OECD Guideline 105: Water Solubility
- Octanol/ water partition coefficient:
  - OECD Guideline 107: Partition Coefficient (n-octanol/water): Shake Flask Method, or
  - OECD Guideline 123: Partition Coefficient (1-Octanol/Water): Slow-Stirring Method, or
  - OECD 117: Partition Coefficient (n-octanol/water) HPLC Method.

Timing: The Company individually, or as a member of the Consortium, is prohibited from manufacturing (which includes importing) the PMN substances 9 months after the Agency has approved all of the pertinent analytical methods and the test protocols submitted by the Consortium, unless the Tier 1, Step 2 testing have been completed and provided to EPA. The time limit may be extended with written approval from EPA; extensions will be granted

Commented [20]: Given the number of substances being examined, the lack of established analytical methods for identifying the presence of the representative substances in the pertinent media, the Consortium thinks it is reasonable for additional time for performing these studies to be provided. Moreover, the trigger should not commence running until the pertinent methods and protocol have been approved by EPA

2 EPA recognizes that substances it might identify such as ions or degradants of interest for further testing may be unique and also might not be commercially available. Thus, the necessary standards for detecting and evaluating the presence of such substances in certain test media may not be available. Accordingly, upon a good faith showing by the Company (or the Consortium on its behalf) that such standards do not exist, EPA will not require testing for such substances. With respect to toxicity testing, if a simple salt is not commercially available for the cation of interest, alternative study designs may need to be discussed.

routinely to accommodate the timing required for Agency review and approval of test protocol. After Tier 1, Step 2 tests have been completed and results provided to EPA, the parties will meet to confer with regard to EPA's evaluation of the results data and to consider which substances will be evaluated and which studies will be performed for purposes of Tier 1, Step 3. Such consultations will begin no later than 4 weeks following EPA's receipt of the final study report for tests completed under Step 2 of Tier 1 and will be completed no later than 6 weeks thereafter. Identification of substances for testing will be determined in accordance with paragraph (d)(2).

Commented [21]: Given the novelty of the testing program and the nature of the substances to be tested, it is reasonable to include this term to ensure delays attributable to the development (and the Agency's review) of test protocols do not disadvantage the PMN submitter/Consortium member

Step 3

EPA, after reviewing the data submitted and meeting with the Consortium, will identify in writing to the Company and the Consortium the test substances, ions, and/or degradants for which the following testing will be performed. Identification of substances for testing will be based on data needs in light of potential risk. The number of substances to be tested may be fewer than, but will not exceed, the number of substances tested in the preceding Step. Such testing may include one or all of the following studies:

- OPPTS Test Guideline 835.5270: Indirect Photolysis Screening Test
- OECD Test Guideline 301: Ready Biodegradability,
- OPPTS 835.3215 Inherent Biodegradability Concawe Test

The biodegradation testing must be carried out with the addition of a chemical-specific analytical method to determine degradation rate.

Timing: The Company individually, or as a member of the Consortium, is prohibited from manufacturing (which includes importing) the PMN substances beyond 9 months after the Agency has approved all of the pertinent analytical methods and the test protocols submitted by the Consortium, unless the Tier 1, Step 3 testing have been completed and provided to EPA. The time limit may be extended with written approval from EPA; extensions will be granted routinely to accommodate the timing required for Agency review and approval of test protocol. After Tier 1, Step 3 tests have been completed and results provided to EPA, the parties will meet to confer with regard to EPA's evaluation of the results data and to consider which substances will be evaluated and which studies will be performed for purposes of Tier 2a, Step 1. Such consultations will begin no later than 4 weeks following EPA's receipt of the final study report for tests completed under Step 3 of Tier 1 and will be completed no later than 6 weeks thereafter. Identification of substances for subsequent testing will be determined in accordance with paragraph (d)(2).

Commented [22]: Given the number of substances being examined, the lack of established analytical methods for identifying the presence of the representative substances in the pertinent media, the Consortium thinks it is reasonable for additional time for performing these studies to be provided. Moreover, the trigger should not commence running until the pertinent methods and protocol have been approved by EPA.

Tier 2a -Additional Fate, Ecological Hazard and Bioaccumulation

Step 1
If EPA determines, after reviewing the data submitted and meeting with the Consortium, that additional testing is necessary to adequately inform on risk to the environment, EPA will identify in writing to the Company and the Consortium the test substances, ions, and/or degradants for which the following testing will be performed. Identification of substances for testing will be based on data needs in light of potential risk. The number of substances to be tested may be fewer than, but will not exceed, the number of substances tested in the preceding Step. Such testing may include one or all of the following: Additional Fate Testing • OECD Test Guideline 307: Aerobic and Anaerobic Transformation in Soil • OECD Test Guideline 308: Aerobic and Anaerobic Transformation in Aquatic Sediment Systems Timing: If the Company receives written notice from EPA that the Tier 2a testing is necessary, the Company individually, or as a member of the Consortium, is prohibited from manufacturing (which includes importing) the PMN substances 12 months after the PMN submitter's annual production volume of any of the substances subject to this Order exceeds 1,000 kg per year, unless the Tier 2a, Step 1 testing have been completed and provided to EPA. The 12-month period during which the Tier 2a, Step 1 testing must be completed and provided to EPA will begin to run only when the annual production cap for the PMN substances subject to the Order has been exceeded and notice has been provided to EPA of the exceedance. Notice must be provided to EPA no fewer than 30 days before the Company estimates the annual production volume will be exceeded. Failure to timely notify EPA is a violation of the terms of this Order. The time limit may be extended with written approval from EPA; extensions will be granted routinely to accommodate the timing required for Agency review and approval of test protocol. After Tier 2a, Step 1 tests have been completed and results provided to EPA, the parties will meet to confer with regard to EPA's evaluation of the results data and to consider which substances will be evaluated and which studies will be performed for purposes of Tier 2a, Step 2. Such consultations will begin no later than 4 weeks following EPA's receipt of the final study report for tests completed under Step 1 of Tier 2a and will be completed no later than 6 weeks thereafter. Identification of substances for subsequent testing will be determined in accordance with paragraph (d)(2).
Step 2
If EPA determines, after reviewing the data submitted and meeting with the Consortium, that additional testing is necessary to adequately inform on risk to the environment, EPA will identify in writing to the Company and the Consortium the test substances, ions, and/or degradants for which the following testing will be performed. Identification of substances for

Commented [23]: The PAG Consortium considers a more reasonable, and risk-based approach for testing under Tier 2a would be to require such studies on the basis of a particular manufacturing/import volume being exceeded on an annual basis. Such a "volume" based trigger, would take effect only after the PMN submitter exceeds an annual production limit. This would ensure there is "cap" on the quantities of the PAG substances that are manufactured or imported for use in the US on an annual basis.

A provision requiring the PMN submitters to report their annual production volume per PMN substance has been added to the record keeping provisions. This will ensure the Agency and the PMN submitters are mutually aware of the quantities of the PMN substances manufactured or imported per year, including those quantities manufactured for export and which must be counted pursuant to the Consent Order's terms with respect to the volume trigger.

testing will be based on data needs in light of potential risk. The number of substances to be tested may be fewer than, but will not exceed, the number of substances tested in the preceding Step. Such testing may include one or all of the following:

Aquatic Studies

- OECD Test Guideline 201: Freshwater Alga and Cyanobacteria, Growth Inhibition Test Toxicity
- OECD Test Guideline 202: *Daphnia* sp., Acute Immobilisation Test
- OECD Test Guideline 203: Fish, Acute Toxicity Test
- OCSPP Test Guideline 850.1735: Spiked Whole Sediment 10-day Toxicity Test, Freshwater Invertebrates

Bioaccumulation Studies

- OECD Test Guideline 305: Bioconcentration: Flow-through Fish Test
- OECD Test Guideline 315: Bioaccumulation in Sediment-dwelling Benthic Oligochaetes

Depending on the characteristics of the chemical to be tested, EPA may determine that the OECD 305 testing will be a dietary exposure test.

Timing: The Company individually, or as a member of the Consortium, is prohibited from manufacturing (which includes importing) the PMN substances beyond 18 months after the Agency has approved all of the pertinent analytical methods and the test protocols submitted by the Consortium, unless the Tier 2a, Step 2 testing have been completed and provided to EPA. The time limit may be extended with written approval from EPA; extensions will be granted routinely to accommodate the timing required for Agency review and approval of test protocol. After Tier 2a, Step 2 tests have been completed and results provided to EPA, the parties will meet to confer with regard to EPA's evaluation of the results data and to consider which substances will be evaluated and which studies will be performed for purposes of Tier 2a, Step 3. Such consultations will begin no later than 4 weeks following EPA's receipt of the final study report for tests completed under Step 2 of Tier 2a and will be completed no later than 6 weeks thereafter. Identification of substances for subsequent testing will be determined in accordance with paragraph (d)(2).

Step 3

Based on the results of the studies conducted in Tier 2a, Step 2, EPA will determine, after considering all the data and meeting with the Consortium to discuss the results of EPA's

evaluation of the Tier 2a, Step 2 results, whether chronic toxicity tests using aquatic organisms are necessary to more fully characterize risk. If EPA determines that additional testing is necessary to adequately inform on risk to the environment, EPA after meeting with the Consortium, will identify in writing to the Company and the Consortium the test substances, ions, and/or degradants for which the following testing will be performed. The number of substances to be tested may be fewer than, but will not exceed, the number of substances tested in the preceding Step. Such testing may include one or all of the following:

Chronic Aquatic Studies

- OECD Test Guideline 211: *Daphnia magna* Reproduction Test
- OECD Test Guideline 210: Fish, Early-life Stage Toxicity Test

Based on the results of the Spiked Whole Sediment 10-day Toxicity Test, Freshwater Invertebrates (OCSPP test guideline 850.1735) in Tier 2a, Step 2, EPA will determine, after meeting with the Consortium to discuss the results of EPA's analysis, whether life-cycle tests for sediment dwelling organisms are necessary to more fully characterize risk. If EPA determines that additional testing is necessary to adequately inform on risk to the environment, EPA after meeting with the Consortium will identify in writing to the Company and the Consortium the test substances, ions, and/or degradants for which the following testing may be requested. The number of substances to be tested may be fewer than, but will not exceed, the number of substances tested in the preceding Step.

Sediment Studies

- OECD Test Guideline 233: Sediment-Water Chironomid Life-Cycle Toxicity Test Using Spiked Water or Spiked Sediment

Timing: The Company individually, or as a member of the Consortium, is prohibited from manufacturing (which includes importing) the PMN substances beyond 9 months after the Agency has approved all of the pertinent analytical methods and the test protocols submitted by the Consortium for Step 3 tests, unless the Tier 2a, Step 3 testing have been completed and provided to EPA. The time limit may be extended with written approval from EPA; extensions will be granted routinely to accommodate the timing required for Agency review and approval of test protocol.

After Tier 2a, Step 3 tests have been completed and results provided to EPA, the parties will meet to confer with regard to EPA's evaluation of the results data and to consider which substances will be evaluated and which studies will be performed for purposes of Tier 2b, Step 1. Such consultations will begin no later than 4 weeks following EPA's receipt of the final

study report for tests completed under Step 3 of Tier 2a and will be completed no later than 6 weeks thereafter. Identification of substances for subsequent testing will be determined in accordance with paragraph (d)(2).

Tier 2b - Human Health Hazard
Step 1
If EPA determines, after reviewing the data submitted and meeting with the Consortium to discuss the Agency's analysis of the Tier 2a, Step 3 results, that additional testing is necessary to adequately inform on risk to human health, EPA will identify in writing to the Company and the Consortium the test substances, ions, and/or degradants for which the following testing will be performed. The number of substances to be tested may be fewer than, but will not exceed, the number of substances tested in the preceding Step. Such testing will include one or all of the following: • Mitochondrial Toxicity Assay in Mammalian Cells • OECD Test Guideline 471: Bacterial Reverse Mutation Test • OECD Test Guideline 487: In Vitro Mammalian Cell Micronucleus Test Timing: If the Company receives written notice from EPA that the Tier 2b testing is necessary, the Company individually, or as a member of the Consortium, is prohibited from manufacturing (which includes importing) the PMN substances beyond 9 months after the Agency has approved all of the pertinent analytical methods and the test protocols submitted by the Consortium for Step 1 tests unless the Tier 2b, Step 1 testing have been completed and provided to EPA. The time limit may be extended with written approval from EPA; extensions will be granted routinely to accommodate the timing required for Agency review and approval of test protocol. After Tier 2b, Step 1 tests have been completed and results provided to EPA, the parties will meet to confer with regard to EPA's evaluation of the results data and to consider which substances will be evaluated and which studies will be performed for purposes of Tier 2b, Step 2. Such consultations will begin no later than 4 weeks following EPA's receipt of the final study report for tests completed under Step 1 of Tier 2b and will be completed no later than 6 weeks thereafter. Identification of substances for subsequent testing will be determined in accordance with paragraph (d)(2).
Step 2

Commented [24]: The PAG Consortium has added terms to make clear that the Tier 2(b) testing would be required only after the 2(a) testing has been triggered by exceedance of the 1,000 kg./yr. trigger and the 2(a) testing has been completed and submitted by the Consortium and reviewed by EPA.

Based on the results of the testing observed in Tier 2b, Step 1, EPA will determine, after meeting with the Consortium to discuss EPA's evaluation of the Tier 2b, Step 1 results, whether neurotoxicity and developmental studies are necessary to more fully characterize risk. If EPA determines that additional testing is necessary to adequately inform on risk to human health, EPA after meeting with the Consortium, will identify in writing to the Company and the Consortium the test substances, ions, and/or degradants for which the following testing will be performed. The number of substances to be tested may be fewer than, but will not exceed, the number of substances tested in the preceding Step. Such testing will include one or all of the following:

- In Vitro Developmental Toxicity Assay, as reported by Andrews *et al* (1995)
- OCSPP Test Guideline 870.6200: Neurotoxicity Screening Battery (Acute Study)

Timing: The Company individually, or as a member of the Consortium, is prohibited from manufacturing (which includes importing) the PMN substances beyond 12 months after the Agency has approved all of the pertinent analytical methods and the test protocols submitted by the Consortium for Step 2 tests unless the Tier 2b, Step 2 test results have been completed and provided to EPA. The time limit may be extended with written approval from EPA; extensions will be granted routinely to accommodate the timing required for Agency review and approval of test protocol.
After Tier 2b, Step 2 tests have been completed and results provided to EPA, the parties will meet to confer with regard to EPA's evaluation of the results data and to consider which substances will be evaluated and which studies will be performed for purposes of Tier 2b, Step 3. Such consultations will begin no later than 4 weeks following EPA's receipt of the final study report for tests completed under Step 2 of Tier 2b and will be completed no later than 6 weeks thereafter. Identification of substances for subsequent testing will be determined in accordance with paragraph (d)(2)).

Step 3

Depending on the results of the studies observed based on the Tier 2b, Step 2, EPA will determine, after meeting with the Consortium to discuss EPA's evaluation of the Tier 2b, Step 2 results, whether chronic toxicity tests are necessary to more fully characterize risk. If EPA determines that additional testing is necessary to adequately inform on risk to human health, EPA, after meeting with the Consortium will identify in writing to the Company and the Consortium the test substances, ions, and/or degradants for which the following testing will be performed. The number of substances to be tested may be fewer than, but will not exceed, the number of substances tested in the preceding Step. Such testing will include one or all of the following:

• OECD Test Guideline 422: Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test Timing: The Company individually, or as a member of the Consortium, is prohibited from manufacturing (which includes importing) the PMN substances beyond 18 months after the Agency has approved all of the pertinent analytical methods and the test protocols submitted by the Consortium for Step 2 tests unless the Tier 2b, Step 3 testing have been completed and provided to EPA. The time limit may be extended with written approval from EPA; extensions will be granted routinely to accommodate the timing required for Agency review and approval of test protocol.

(e) Test Reports. The Company or the Consortium (acting on behalf of the Company) must: (1) conduct each study in good faith, with due care, and in a scientifically valid manner; (2) promptly furnish to EPA the results of any interim phase of each study, if requested by EPA; and (3) submit the final report of each test (with an additional sanitized copy, if confidential business information is involved) and all underlying data ("the report and data") to EPA at the conclusion of each test. The final report and data must be submitted as a support document for each PMN, using the procedures set out in 40 C.F.R. § 720.40. The final report must contain the contents specified in 40 C.F.R. § 792.185. Underlying data must be submitted to EPA in accordance with the applicable "Reporting," "Data and Reporting," and "Test Report" subparagraphs in the applicable test guidelines. However, for purposes of this Consent Order, the word "should" in those subparagraphs will be interpreted to mean "must" to make clear that performing the applicable procedures and submitting the applicable information are mandatory. EPA will require the submission of raw data such as slides and laboratory notebooks only if EPA finds, on

the basis of professional judgment, that an adequate evaluation of the study cannot take place in the absence of these items.

(f) Testing Waivers. The Company or the Consortium (acting on behalf of the Company) is not required to conduct a study specified in paragraph (d) of this Testing section if notified in writing by EPA that it is unnecessary to conduct that study. Upon written request from the Company or the Consortium (acting on behalf of the Company), EPA may provide a written waiver of the GLP requirement for a study specified in paragraph (d).

(g) Equivocal Data. If EPA finds that the data generated by a study are scientifically equivocal, the Company may continue to manufacture the PMN substances beyond the applicable time period specified in Testing section paragraph (d)(2). To seek relief from any other restrictions of this Consent Order, the Company or the Consortium (acting on behalf of the Company) may make a second attempt to obtain unequivocal data by reconducting the study under the conditions specified in paragraphs (b), (c), and (e) (except that the study may be submitted after reaching the applicable time period specified in this Testing section paragraph (d)(2)). The testing requirements may be modified, as necessary to permit a reasoned evaluation of the risks presented by the PMN substances, only by mutual consent of EPA and the Company or Consortium.

(h) EPA Determination of Invalid Data.

(1) Except as described in subparagraph (h)(2), if, within 6 weeks of EPA's receipt of a test report and data, the Company or the Consortium receives written notice that EPA finds that the data generated by a study are scientifically invalid, the Company is prohibited from further manufacture of the PMN substances beyond the applicable time period specified in this Testing section paragraph (d)(2) without EPA's written consent.

(2) The Company may continue to manufacture the PMN substances beyond the applicable time period specified in Testing section paragraph (d)(2) only if so notified, in writing, by EPA in response to the Company's compliance with either of the following subparagraphs (h)(2)(i) or (h)(2)(ii).

(i) If there is sufficient time to reconduct the study in compliance with paragraphs (b), (c), and (e) before exceeding the applicable time period specified in Testing section paragraph (d)(2), the Company or the Consortium (acting on behalf of the Company) may reconduct the study. If there is insufficient time to reconduct the study in compliance with paragraphs (b), (c), and (e) before exceeding the applicable time period specified in Testing section paragraph (d)(2), the Company may exceed the time period, but must otherwise comply with paragraphs (b), (c), and (e), and the Company or the Consortium (acting on behalf of the Company) must submit the report and data to EPA within a reasonable period of time, all as specified by EPA in the notice described in subparagraph (h)(1). EPA will respond to the

Company or the Consortium, in writing, within 6 weeks of receiving the Company's or Consortium's report and data.

(ii) The Company or the Consortium may, within 4 weeks of receiving from EPA the notice described in subparagraph (h)(1), submit to EPA a written report refuting EPA's finding. EPA will respond to the Company or the Consortium, in writing, within 4 weeks of receiving the Company's or the Consortium's report.

(i) Company Determination of Invalid Data.

(1) Except as described in subparagraph (i)(2), if the Company or the Consortium becomes aware that circumstances clearly beyond the control of the Company, Consortium or laboratory will prevent, or have prevented, development of scientifically valid data under the conditions specified in paragraphs (c) and (e), the Company remains prohibited from further manufacture of the PMN substances beyond the applicable time period specified in Testing section paragraph (d)(2) without EPA's written consent.

(2) The Company or the Consortium may submit to EPA, within 2 weeks of first becoming aware of such circumstances, a written statement explaining why circumstances clearly beyond the control of the Company or the Consortium or laboratory will cause or have caused development of scientifically invalid data. EPA will notify the Company or the Consortium of its response, in writing, within 4 weeks of receiving the Company or the Consortium's report. EPA's written response may either:

(i) allow the Company to continue to manufacture the PMN substances beyond the applicable time period specified in this Testing section paragraph (d)(2), or

(ii) require the Company or the Consortium (acting on behalf of the Company) to continue to conduct, or to reconduct, the study in compliance with paragraphs (b), (c), and (e), if there is sufficient time to conduct or reconduct the study and submit the report and data to EPA before exceeding the applicable time period specified in Testing section paragraph (d)(2). If there is insufficient time for the Company or the Consortium to comply with paragraphs (b), (c), and (e) before exceeding the applicable time period specified in Testing section paragraph (d)(2), the Company may exceed the time period, but must otherwise comply with paragraphs (b), (c), and (e), and must submit the report and data to EPA within a reasonable period of time, all as specified by EPA in the notice described in subparagraph (i)(2). EPA will respond to the Company or Consortium, in writing, within 6 weeks of receiving the Company or the Consortium's report and data, as to whether the Company may continue to manufacture beyond the applicable time period specified in Testing section paragraph (d)(2).

(j) Unreasonable Risk.

EPA may notify the Company or Consortium in writing that EPA finds that the data generated by a study (including studies not performed or information not generated under this Consent Order) are scientifically valid and unequivocal and indicate that, despite the terms of this Consent Order, the PMN substances present or may present an unreasonable risk of injury to

human health or the environment. In addition, if during review of the studies performed under this Consent order on the five specified "test substances", EPA determines that the results of the study(ies) do not provide sufficient data on the hazards or potential hazards of any of the PMN substances which have not been subject to the tiered testing performed under this Consent Order, then EPA may also send notice to the Company. EPA's notice may specify that the Company undertake certain actions concerning further testing, manufacture, processing, distribution, use and/or disposal of the PMN substances to mitigate exposures to or to better characterize the risks presented by the PMN substances. Within 2 weeks from receipt of such a notice, the Company must cease all manufacture, processing, distribution, use and disposal of the PMN substances, unless either:

(1) within 2 weeks from receipt of the EPA notice, the Company complies with such requirements as the notice specifies; or

(2) within 2 weeks from receipt of the EPA notice, the Company submits to EPA a written report refuting EPA's finding and/or the appropriateness of any additional requirements imposed by EPA. The Company may continue to manufacture, process, distribute, use and dispose of the PMN substances in accordance with the terms of this Consent Order pending EPA's response to the Company's written report. EPA will respond to the Company, in writing, within 2 weeks of receiving the Company's report. Within 2 weeks of receipt of EPA's written response, the Company must comply with any requirements imposed by EPA's response or cease all manufacture, processing, distribution, use and disposal of the PMN substances.

(k) Other Requirements. Regardless of the satisfaction of any other conditions in this Testing section, the Company must continue to obey all the terms of this Consent Order until otherwise notified in writing by EPA. The Company may, based upon submitted test data or other relevant information, petition EPA to modify or revoke provisions of this Consent Order pursuant to Section VI of this Consent Order.

PROTECTION IN THE WORKPLACE

Commented [25]: This draft is the first time the PAG Consortium members have seen this provision and seek to confirm the individual Consent Orders the PMN submitters will receive will be tailored to the conditions of use described in their respective PMNs.

(a) Establishment of Program. During manufacturing, processing, and use of the PMN substances at any site controlled by the Company (including any associated packaging and storage and during any cleaning or maintenance of equipment associated with the PMN substances), the Company must establish a program whereby:

(1) General Dermal Protection. Engineering control measures (e.g. enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g. workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible to each person who is reasonably likely to be dermally exposed in the work area to the PMN substances through direct handling of the PMN substances or through contact with equipment on which the PMN substances may exist, or because the PMN substances becomes airborne in a form listed in subparagraph (a)(5) of this section. Where engineering, work practice, and administrative controls are not feasible or, if feasible, do not

Commented [26]: The discussion of the human health effects assessment appearing earlier in the model Order states that dermal absorption will be nil. The Consortium requests clarification on why this dermal protection provision is necessary in the model Order. Should this section be omitted?

prevent exposure, each person subject to this exposure must be provided with, and is required to wear, personal protective equipment that provides a barrier to prevent dermal exposure to the PMN substances in the specific work area where it is selected for use. Each such item of personal protective equipment must be selected and used in accordance with Occupational Safety and Health Administration ("OSHA") dermal protection requirements at 29 C.F.R. §§ 1910.132, 1910.133, and 1910.138.

(2) Specific Dermal Protective Equipment. The dermal protective equipment required by subparagraph (a)(1) of this section must include, but is not limited to, the following items:

(i) Gloves.

(ii) Chemical goggles or equivalent eye protection.

(3) Demonstration of Imperviousness. The Company must demonstrate that each item of chemical protective clothing selected, including gloves, provides an impervious barrier to prevent dermal exposure during normal and expected duration and conditions of exposure within the work area. The Company may make this demonstration by any one or a combination of the following:

(i) Permeation Testing. Testing the material used to make the chemical protective clothing and the construction of the clothing to establish that the protective clothing will be impervious for the expected duration and conditions of exposure. The testing must subject the chemical protective clothing to the expected conditions of exposure, including the likely combinations of chemical substances to which the clothing may be exposed in the work

area. Permeation testing may be conducted according to the American Society for Testing and Materials ("ASTM") F739 "Standard Test Method for Permeation of Liquids and Gases through Protective Clothing Materials under Conditions of Continuous Contact." Results must be reported as the cumulative permeation rate as a function of time, and must be documented in accordance with ASTM F739 using the format specified in ASTM F1194-99(2010) "Standard Guide for Documenting the Results of Chemical Permeation Testing of Materials Used in Protective Clothing Materials." Gloves may not be used for a time period longer than they are actually tested and must be replaced at the end of each work shift during which they are exposed to the PMN substances.

(ii) Manufacturer's Specifications. Evaluating the specifications from the manufacturer or supplier of the chemical protective clothing, or of the material used in construction of the clothing, to establish that the chemical protective clothing will be impervious to the PMN substances alone and in likely combination with other chemical substances in the work area.

RISK NOTIFICATION

(a) If as a result of the test data required under the terms of this Consent Order, the Company becomes aware that the PMN substances may present a risk of injury to health or the environment (or is so notified by EPA), the Company must incorporate this new information, and any information on methods for protecting against such risk, into an SDS or MSDS, as described in 40 C.F.R. § 721.72(c), within 90 days from the time the Company becomes aware of the new

information. If the PMN substances are not being manufactured (which includes import), processed, or used in the Company's workplace, the Company must add the new information to an SDS or MSDS before the PMN substances are reintroduced into the workplace.

(b) The Company must ensure that persons who will receive the PMN substances from the Company, or who have received the PMN substances from the Company within 5 years from the date the Company becomes aware of the new information described in paragraph (a) of this section, are provided an SDS or MSDS containing the information required under paragraph (a) within 90 days from the time the Company becomes aware of the new information.

HAZARD COMMUNICATION PROGRAM

(a) Written Hazard Communication Program. The Company must develop and implement a written hazard communication program for the PMN substances in each workplace. The written program will, at a minimum, describe how the requirements of this section for labels, SDSs or MSDSs, and other forms of warning material will be satisfied. The Company must make the written hazard communication program available, upon request, to all employees, contractor employees, and their designated representatives. The Company may rely on an existing hazard communication program, including an existing program established under the OSHA Hazard Communication Standard (29 C.F.R. § 1910.1200), to comply with this paragraph provided that

the existing hazard communication program satisfies the requirements of this section. The written program must include the following:

(1) A list of chemical substances known to be present in the work area which are subject to a consent order or order issued under § 5 of TSCA to the Company, or to a significant new use rule ("SNUR") issued under § 5(a)(2) of TSCA and 40 C.F.R. pt. 721, subpt. E. The list must be maintained in each work area where the PMN substances are known to be present and must use the identity provided on the SDS or MSDS for the PMN substances required under paragraph (c) of this section. The list may be compiled for the workplace or for individual work areas. If the Company is required either by another consent order or order issued under § 5 of TSCA, or by a SNUR issued under TSCA § 5(a)(2) and 40 C.F.R. pt. 721, subpt. E, to maintain a list of substances, the lists must be combined with the list under this subparagraph.

(2) The methods the Company will use to inform employees of the hazards of non-routine tasks involving the PMN substances (e.g., cleaning of reactor vessels), and the hazards associated with the PMN substances contained in unlabeled pipes in their work area.

(3) The methods the Company will use to inform contractors of the presence of the PMN substances in the Company's workplace and of the provisions of this Consent Order if employees of the contractor work in the Company's workplace and are reasonably likely to be exposed to the PMN substances while in the Company's workplace.

(b) Labeling.

(1) The Company must ensure that each container of the PMN substances in the workplace are labeled in accordance with this subparagraph (b)(1).(i) The label must, at a minimum, contain the following information:

(A) A statement of the health hazards(s) and precautionary measure(s) identified in paragraph (f) of this section. These statements may be supplemented with any health hazard(s) and precautionary measure(s) identified by the Company.

Commented [27]: The PAG Consortium requests clarification of whether this should be a cross reference to paragraph (e) rather than (f). If so, corrections are needed elsewhere in this section where highlighted.

(B) The identity by which the PMN substance may be commonly recognized.

(C) A statement of the environmental hazards(s) and precautionary measure(s) identified in paragraph (f) of this section. These statements may be supplemented with any environmental hazard(s) and precautionary measure(s) identified by the Company.

(D) A statement of exposure and precautionary measure(s), if any, identified either in paragraph (f) of this section. These statements may be supplemented with any exposure and precautionary measure(s) identified by the Company

(ii) The Company may use signs, placards, process sheets, batch tickets, operating procedures, or other such written materials in lieu of affixing labels to individual stationary process containers, as long as the alternative method identifies the containers to which it is applicable and conveys information specified by subparagraph (b)(1)(i) of this section. Any written materials must be readily accessible to the employees in their work areas throughout each work shift.

(iii) The Company need not label portable containers into which the PMN substances are transferred from labeled containers, and which are intended only for the immediate use of the employee who performs the transfer.

(iv) The Company must not remove or deface an existing label on containers of the PMN substances obtained from persons outside the Company unless the container is immediately re-labeled with the information specified in subparagraph (b)(1)(i) of this section.

(2) The Company must ensure that each container of the PMN substances leaving its workplace for distribution in commerce are labeled in accordance with this subparagraph (b)(2).

(i) The label must, at a minimum, contain the following information:

(A) The information prescribed in subparagraph (b)(1)(i) of this section.

(B) The name and address of the manufacturer or a responsible party who can provide additional information on the PMN substances for hazard evaluation and any appropriate emergency procedures.

(ii) The label must not conflict with the requirements of the Hazardous Materials Transportation Act (18 U.S.C. 1801 et. seq.) and regulations issued under that Act by the Department of Transportation.

(3) The label, or alternative forms of warning, must be legible and prominently displayed.

(4) The label, or alternative forms of warning, must be printed in English; however, the information may be repeated in other languages.

(5) If the label or alternative form of warning is to be applied to a mixture containing the PMN substance in combination with any other substance that is either subject to another consent order or order issued under § 5 of TSCA to the Company, SNUR issued under § 5(a)(2) of TSCA and 40 C.F.R. pt. 721, subpt. E, or defined as a "hazardous chemical" under the OSHA Hazard Communication Standard (29 C.F.R. § 1910.1200), the Company may prescribe on the label, SDS or MSDS, or alternative form of warning, the measures to control worker exposure or environmental release which the Company determines provide the greatest degree of protection. However, should these control measures differ from the applicable measures required under this Consent Order, the Company must seek a determination of equivalency for such alternative control measures pursuant to 40 C.F.R. § 721.30 before prescribing them under this subparagraph (b)(5).

(6) If the Company becomes aware of any significant new information regarding the hazards of the PMN substances or ways to protect against the hazards, this new information must be added to the label within 3 months from the time the Company becomes aware of the new information. If the PMN substances are not being manufactured (defined by statute to include import), processed, or used in the Company's workplace, the Company must add the new information to the label before the PMN substances are reintroduced into the workplace.

(c) Safety Data Sheets or Material Safety Data Sheets.

(1) The Company must obtain or develop an SDS or MSDS for the PMN substances.

(2) The SDS or MSDS must contain, at a minimum, the following information:

(i) The identity used on the container label of the PMN substances under this section, and, if not claimed confidential, the chemical and common name of the PMN substances. If the chemical and common names are claimed confidential, a generic chemical name must be used.

(ii) Physical and chemical characteristics of the PMN substances known to the Company, (e.g., vapor pressure, flash point).

(iii) The physical hazards of the PMN substances known to the Company, including the potential for fire, explosion, and reactivity.

(iv) The potential human and environmental hazards as specified in paragraph (f) of this section.

(v) Signs and symptoms of exposure, and any medical conditions which are expected to be aggravated by exposure to the PMN substances known to the Company.

(vi) The primary routes of exposure to the PMN substances.

(vii) Precautionary measures to control worker exposure and/or environmental release required by this Consent Order, or alternative control measures which EPA has determined under 40 C.F.R. § 721.30 provide substantially the same degree of protection as the identified control measures.

(viii) Any generally applicable precautions for safe handling and use of the PMN substances which are known to the Company, including appropriate hygienic practices,

protective measures during repair and maintenance of contaminated equipment, and procedures for response to spills and leaks.

(ix) Any generally applicable control measures which are known to the Company, such as appropriate engineering controls, work practices, or personal protective equipment.

(x) Emergency first aid procedures known to the Company.

(xi) The date of preparation of the SDS or MSDS or of its last revision.

(xii) The name, address, and telephone number of the Company or another responsible party who can provide additional information on the PMN substances and any appropriate emergency procedures.

(3) If no relevant information is found or known for any given category on the SDS or MSDS, the Company must mark the SDS or MSDS to indicate that no applicable information was found.

(4) Where multiple mixtures containing the PMN substances have similar compositions (i.e., the chemical ingredients are essentially the same, but the specific composition varies from mixture to mixture) and similar hazards, the Company may prepare one SDS or MSDS to apply to all of these multiple mixtures.

(5) If the Company becomes aware of any significant new information regarding the hazards of the PMN substances or ways to protect against the hazards, this new information must be added to the SDS or MSDS within 3 months from the time the Company becomes aware of

the new information. If the PMN substances are not being manufactured (defined by statute to include import), processed, or used in the Company's workplace, the Company must add the new information to the SDS or MSDS before the PMN substance is reintroduced into the workplace.

(6) The Company must ensure that persons receiving the PMN substances from the Company are provided an appropriate SDS or MSDS with their initial shipment and with the first shipment after an SDS or MSDS is revised. The Company may either provide the SDS or MSDS with the shipped containers or send it to the person prior to or at the time of shipment.

(7) The Company must maintain a copy of the SDS or MSDS in its workplace and must ensure that it is readily accessible during each work shift to employees when they are in their work areas.

(8) The SDS or MSDS may be kept in any form, including as operating procedures, and may be designed to cover groups of substances in a work area where it may be more appropriate to address the potential hazards of a process rather than individual substances. However, in all cases, the required information must be provided for the PMN substances and must be readily accessible during each work shift to employees when they are in their work areas.

(9) The SDS or MSDS must be printed in English; however, the information may be repeated in other languages.

(d) Employee Information and Training. The Company must ensure that employees are provided with information and training on the PMN substances. This information and training

must be provided at the time of each employee's initial assignment to a work area containing the PMN substances and whenever the PMN substances are introduced into the employee's work area for the first time.

(1) The information provided to employees under this paragraph must include:

(i) The requirements of this section.

(ii) Any operations in the work area where the PMN substances are present.

(iii) The location and availability of the written hazard communication program required under paragraph (a) of this section, including the list of substances required by subparagraph (a)(1) of this section and SDSs or MSDSs required by paragraph (c) of this section.

(2) The training provided to employees must include:

(i) Methods and observations that may be used to detect the presence or release of the PMN substances in or from an employee's work area (such as exposure monitoring conducted by the Company, continuous monitoring devices, visual appearance, or odor of the PMN substances when being released).

(ii) The potential human health and environmental hazards of the PMN substances as specified in paragraph (f) of this section.

Commented [28]: The PAG Consortium requests clarification of whether this should be a cross reference to paragraph (e), rather than (f).

(iii) The measures employees can take to protect themselves and the environment from the PMN substances, including specific procedures the Company has implemented to protect employees and the environment from exposure to the PMN substances, including appropriate work practices, emergency procedures, personal protective equipment, engineering

controls, and other measures to control worker exposure and/or environmental release required under this Consent Order, or alternative control measures which EPA has determined under 40 C.F.R. § 721.30 provide the same degree of protection as the specified control measures.

(iv) The requirements of the hazard communication program developed by the Company under this section, including an explanation of the labeling system and the SDS or MSDS required by this section and guidance on obtaining and using appropriate hazard information.

(e) Human Health, Environmental Hazard, Exposure, and Precautionary Statements. The following human health and environmental hazard and precautionary statements must appear on each label as specified in paragraph (b) and the SDS or MSDS as specified in paragraph (c) of this section:

(1) Human health hazard statements. This substance may cause:

(i) Acute toxicity

(ii) Skin Sensitization

(iii) Serious Eye Damage

(iv) Specific Target Organ Toxicity

(v) Reproductive Toxicity

(vi) Skin irritation

Commented [29]: This draft is the first time PAG Consortium members have seen these terms. The Consortium understands and seeks to confirm that the Agency will include only those human health effects understood to be potentially applicable to the PMN substance subject to the Consent Order.

(2) Human hazard precautionary statements. When using this substance:

(i) avoid skin contact.

(ii) avoid breathing the substance.

(iii) avoid ingestion.

(v) use skin protection.

(3) Environmental hazard statements. This substance may be:

(i) toxic to fish.

(ii) toxic to aquatic organisms.

(4) The human and environmental hazard and precautionary statement on the label prepared pursuant to paragraph (b) of this section must be followed by the statement: "See the SDS or MSDS for details."

(5) The Company may use alternative hazard and warning statements that meet the criteria of the Globally Harmonized System (GHS) and OSHA Hazard Communication Standard.

(f) Existing Hazard Communication Program. The Company need not take additional actions if existing programs and procedures satisfy the requirements of this section.

(g) De Minimis Concentrations. The Hazard Communications provisions of this Order do not apply to quantities of the PMN substance that are (1) present in the work area only as a mixture and (2) at a concentration not to exceed 1.0 percent by weight or volume (0.1 percent by weight or volume if the PMN substance is identified as a potential carcinogen in the Hazard

Communication Program section of this Order). This exemption is not available if the Company has reason to believe that, during intended activities, the PMN substance in the mixture may be reconcentrated above the 1.0 or 0.1 percent level, whichever applies.

MANUFACTURING

(a)(1) Prohibition. The Company must not cause, encourage, or suggest the manufacture (which includes import) of the PMN substances by any other person.

(2) Sunset Following SNUR. Subparagraph (a)(1) will expire 75 days after promulgation of a final significant new use rule ("SNUR") governing the PMN substances under § 5(a)(2) of TSCA unless the Company is notified on or before that day of an action in a Federal Court seeking judicial review of the SNUR. If the Company is so notified, subparagraph (a)(1) will not expire until EPA notifies the Company in writing that all Federal Court actions involving the SNUR have been resolved and the validity of the SNUR affirmed.

(3) Notice of SNUR. If and when EPA promulgates a final SNUR for the PMN substances and subparagraph (a)(1) expires in accordance with subparagraph (a)(2), the Company must notify each person whom it causes, encourages or suggests to manufacture the PMN substances of the existence of the SNUR.

(b) The Company must not manufacture the PMN substances

Commented [30]: The PAG Consortium understands and requests EPA confirm that these terms will be modified based on the conditions of use described in the PMN submitted. Thus, a restriction on manufacture in the US will not be included in a proposed Consent Order if the PMN described domestic manufacture.

(1) In the United States;

(2) Beyond an annual manufacture (which includes import) volume of _____;

(3) Other than in solution

Commented [31]: As noted previously, the PAG Consortium understands limitations will be tailored to reflect the conditions of use described in the submitter's PMN. Thus, restrictions on physical form will not be include in a proposed Consent Order unless there is a risk-basis for doing so and the limitation will be consistent with respect to the physical state for the substance described in the PMN submitted.

Similarly, we understand the conditions of use in each PMN will be reflected in the draft Orders the PMN submitters receive and in any Modifications that will be made to refer to and incorporate subsequent PMNs submitted that fall within scope. For example, draft Orders will not prohibit domestic production if the PMN submitter's PMN described US manufacture as a condition of use.

PROCESSING

(a) The Company may not process the PMN substances:

in any way that generates dust, mist or aerosol in a non-enclosed process;

USE

(a) The Company may not use the PMN substances other than as described in the PMN.

DISTRIBUTION

(a) Export Notice Requirement. No later than the date of distribution, the Company must notify in writing any person to whom it distributes the PMN substances that, due to the issuance of this Consent Order, the PMN substances are subject to the export notification requirements of TSCA § 12(b) and 40 C.F.R. pt. 707, subpt. D. Such notice must contain, in the form in which it appears in this Consent Order, the following information: (1) the PMN number, and (2) either (A) the specific chemical identities of the PMN substances, or (B) if the specific chemical identities are confidential, the generic chemical identities.

(b) Distribution Requirements. Except as provided in paragraph (c), the Company is permitted to distribute the PMN substances outside the Company, other than for disposal, only to a person who has agreed in writing prior to the date of distribution, to:

(1) Notify in writing any person to whom it distributes the PMN substances that, due to the issuance of this Consent Order under § 5(e) of TSCA, the PMN substances are subject to the export notification requirements of TSCA § 12(b) and 40 C.F.R. pt. 707, subpt. D. Such notice must contain, in the form in which it appears in this Consent Order, the following information: (1) the PMN numbers, and (2) either (A) the specific chemical identities of the PMN substances, or (B) if the specific chemical identities are confidential, the generic chemical identities.

(2) Not further distribute the PMN substances to any other person, other than for disposal.

(5) Not process the PMN substances in any way that generates dust, mist or aerosol in a non-enclosed process.

(6) Not use the PMN substances Other than as described in the PMN.

Commented [32]: The PAG Consortium considers these terms to be unnecessary for the customers to which the PMN submitters provide formulated products. The entities that receive the PAG substances typically do so in mixtures in which the PAG substance might be present in very low concentrations and which will not identify the PMN chemical by name or other form of identification. Thus, the user of the PAG is unlikely to have a means to specifically adjust its existing Haz. Com. Program for purposes of the Consent Order. The Conditions of use at semiconductor manufacturing sites are such that direct human exposures to the PAG substances are not expected to occur.

(c) Temporary Transport and Storage. Notwithstanding paragraph (b), the Company may distribute the PMN substances outside the Company for temporary transport and storage in sealed containers provided the following three conditions are met:

(1) Subsequent to any such exempt temporary transport or storage of sealed containers,

the PMN substances may be distributed only to the Company or a person who has given the Company the written agreement required by paragraph (b).

(2) Any human exposure or environmental release resulting from opening the sealed containers and removing or washing out the PMN substances may occur only while the PMN substances are in the possession and control of the Company or a person who has given the Company the written agreement required by paragraph (b).

(3) The sealed containers must be labeled in accordance with paragraph (b)(2) of the Hazard Communication Program section of this Consent Order.

(d) Recipient Non-Compliance. If, at any time after commencing distribution in commerce of the PMN substances, the Company obtains knowledge that a recipient of the PMN substances has failed to comply with any of the conditions specified in paragraph (b) of this Distribution section or, after paragraph (b) expires in accordance with subparagraph (e)(1), has engaged in a significant new use of the PMN substances (as defined in 40 C.F.R. pt. 721, subpt. E) without submitting a significant new use notice to EPA, the Company must cease supplying the PMN substances to that recipient, unless the Company is able to document each of the following:

(1) That the Company has, within 5 working days, notified the recipient in writing that the recipient has failed to comply with any of the conditions specified in paragraph (b) of this Distribution section, or has engaged in a significant new use of the PMN substances without submitting a significant new use notice to EPA.

(2) That, within 15 working days of notifying the recipient of the noncompliance, the Company received from the recipient, in writing, a statement of assurance that the recipient is aware of the terms of paragraph (b) of this Distribution section and will comply with those terms, or is aware of the terms of the significant new use rule for the PMN substances and will not engage in a significant new use without submitting a significant new use notice to EPA.

(3) If, after receiving a statement of assurance from a recipient under subparagraph (d)(2) of this Distribution section, the Company obtains knowledge that the recipient has failed to comply with any of the conditions specified in paragraph (b) of this Distribution section, or has engaged in a significant new use of the PMN substances without submitting a significant new use notice to EPA, the Company must cease supplying the PMN substances to that recipient, must notify EPA of the failure to comply, and is permitted to resume supplying the PMN substances to that recipient only upon written notification from the Agency.

(e) Sunset Following SNUR and Notification of SNUR. (1) Paragraphs (b) and (c) of this Distribution section will expire 75 days after promulgation of a final SNUR for the PMN substances under § 5(a)(2) of TSCA, unless the Company is notified on or before that day of an action in a Federal Court seeking judicial review of the SNUR. If the Company is so notified, paragraphs (b) and (c) of this Distribution section will not expire until EPA notifies the Company in writing that all Federal Court actions involving the SNUR have been resolved and the validity of the SNUR affirmed.

(2) When EPA promulgates a final SNUR for the PMN substances and paragraph (b) of this Distribution section expires in accordance with subparagraph (e)(1), the Company must notify each person to whom it distributes the PMN substances of the existence of the SNUR. Such notification must be in writing and must specifically include all limitations contained in the SNUR which are defined as significant new uses, and which would require significant new use notification to EPA for the PMN substances. Such notice must also reference the publication of the SNUR for the PMN substances in either the Federal Register or the Code of Federal Regulations.

III. RECORDKEEPING

(a) Records. The Company must maintain the following records until 5 years after the date they are created and must make them available for inspection and copying by EPA in accordance with § 11 of TSCA:

(1) Exemptions. Records documenting that the PMN substances did in fact qualify for any one or more of the exemptions described in Section I, Paragraph (b) of this Consent Order. Such records must satisfy all the statutory and regulatory recordkeeping requirements applicable to the exemption being claimed by the Company. Any amounts or batches of the PMN substances eligible for the export only exemption in Section I, Paragraph (b)(1) of this Consent Order are exempt from all the requirements in this Recordkeeping section, if the Company maintains, for 5 years from the date of their creation, copies of the export label and export notice

to EPA, required by TSCA §§ 12(a)(1)(B) and 12(b), respectively. Any amounts or batches of the PMN substances eligible for the research and development exemption in Section I, Paragraph (b)(2) of this Consent Order are exempt from all the requirements in this Recordkeeping section, if the Company maintains, for 5 years from the date of their creation, the records required by 40 C.F.R. § 720.78(b). For any amounts or batches of the PMN substances claimed to be eligible for any other exemption described in Section I, Paragraph (b) of this Consent Order, the Company must keep records demonstrating qualification for that exemption as well as the records specified in paragraphs (2) and (3) below, but is exempt from the other recordkeeping requirements in this Recordkeeping section;

(2) Records documenting the manufacture (which includes import) volume of the PMN substances and the corresponding dates of manufacture. Records documenting the Company's annual manufacture (import) volume will be submitted to EPA annually by January 31 of the following year, for purposes of confirming whether the production volume limits, and testing trigger have been exceeded;

Commented [33]: This term has been added for purposes of providing information to EPA needed to confirm annual production volume limits and testing trigger requirements have not been exceeded.

(3) Records documenting the names and addresses (including shipment destination address, if different) of all processors outside the site of manufacture (which includes import) to whom the Company directly sells or transfers the PMN substances, the date of each sale or transfer, and the quantity of the PMN substances sold or transferred on such date;

(4) Records documenting the address of all sites of manufacture (which includes import), processing, and use;

(5) Records documenting establishment and implementation of a program for the use of any applicable personal protective equipment required pursuant to the Protection in the Workplace section of this Consent Order;

(6) Records documenting the determinations required by the Protection in the Workplace section of this Consent Order that chemical protective clothing is impervious to the PMN substances;

(7) Records documenting establishment and implementation of the hazard communication program required by the Hazard Communication Program section of this Consent Order;

(8) Copies of labels required under the Hazard Communication Program section of this Consent Order;

(9) Copies of Material Safety Data Sheets required by the Hazard Communication Program section of this Consent Order;

(10) Records documenting compliance with any applicable manufacturing, processing, use, and distribution restrictions in the Manufacturing, Processing, Use, and Distribution sections of this Consent Order;

(11) Copies of any Transfer Documents and notices required by the Successor Liability section of this Consent Order, if applicable; and,

(12) The Company must keep a copy of this Consent Order at each of its sites where the PMN substances are manufactured (which includes import).

(b) Applicability. The provisions of this Recordkeeping Section are applicable only to activities of the Company and its Contract Manufacturer within the United States, if applicable, and not to activities of the Company's customers.

(c) OMB Control Number. Under the Paperwork Reduction Act and its regulations at 5 C.F.R. pt. 1320, particularly 5 C.F.R. § 1320.5(b), the Company is not required to respond to this "collection of information" unless this Consent Order displays a currently valid control number from the Office of Management and Budget ("OMB"), and EPA so informs the Company. The "collection of information" required in this TSCA § 5(e) Consent Order has been approved under currently valid **OMB Control Number 2070-0012.**

IV. REQUESTS FOR PRE-INSPECTION INFORMATION

(a) EPA's Request for Information. Pursuant to § 11 of TSCA and 40 C.F.R. § 720.122, EPA may occasionally conduct on-site compliance inspections of Company facilities and conveyances associated with the PMN substances. To facilitate such inspections, EPA personnel may contact the Company in advance to request information pertinent to the scheduling and conduct of such inspections. Such requests may be written or oral. The types of information that EPA may request include, but are not limited to, the following:

(1) Expected dates and times when the PMN substances will be in production within the subsequent 12 months;

(2) Current workshift schedules for workers who are involved in activities associated with the PMN substances and may reasonably be exposed to the PMN substances;

(3) Current job titles or categories for workers who are involved in activities associated with the PMN substances and may reasonably be exposed to the PMN substances;

(4) Existing exposure monitoring data for workers who are involved in activities associated with the PMN substances and may reasonably be exposed to the PMN substances;

(5) Records required by the Recordkeeping section of this Consent Order; and/or,

(6) Any other information reasonably related to determining compliance with this Consent Order or conducting an inspection for that purpose.

(b) Company's Response. The Company must respond to such requests within a reasonable period of time, but in no event later than 30 days after receiving EPA's request. When requested in writing by EPA, the Company's response must be in writing. To the extent the information is known to or reasonably ascertainable by the Company at the time of the request, the Company's response must demonstrate a good faith effort to provide reasonably accurate and detailed answers to all of EPA's requests.

(c) Confidential Business Information. Any Confidential Business Information ("CBI") that the

Company submits to EPA pursuant to paragraph (b) will be protected in accordance with §14 of TSCA and 40 C.F.R. pt. 2, subpt. B. In order to make a confidentiality claim for information submitted to EPA, an authorized official of the Company must certify that it is true and accurate that the Company has:

(1) Taken reasonable measures to protect the confidentiality of the information;

(2) Determined that the information is not required to be disclosed or otherwise made available to the public under any other Federal law;

(3) A reasonable basis to conclude that the disclosure of the information is likely to cause substantial harm to the competitive position of the Company; and

(4) A reasonable basis to believe that the information is not readily discoverable through reverse engineering.

CBI claims for chemical identity must be accompanied by a generic chemical identity, which may be that used for the PMN. CBI claims must be accompanied by substantiations in accordance with TSCA § 14(c)(5). Guidance on substantiating CBI claims may be found at [HYPERLINK "https://www.epa.gov/tsca-cbi/substantiating-cbi-claims-under-tsca-time-initial-submission"].

V. SUCCESSOR LIABILITY UPON TRANSFER OF CONSENT ORDER

(a) Scope. This section sets forth the procedures by which the Company's rights and obligations under this Consent Order may be transferred when the Company transfers its interests in the

PMN substances, including the right to manufacture the PMN substances, to another person outside the Company (the "Successor in Interest").

(b) Relation of Transfer Date to Notice of Commencement ("NOC").

(1) Before NOC. If the transfer from the Company to the Successor in Interest is effective before EPA receives a notice of commencement of manufacture or import ("NOC") for the PMN substances from the Company pursuant to 40 C.F.R. § 720.102, the Successor in Interest must submit a new PMN to EPA and comply fully with § 5(a)(1)(B) of TSCA and 40 C.F.R. pt. 720 before commencing manufacture (which includes import) of the PMN substances.

(2) After NOC. If the transfer from the Company to the Successor in Interest is effective after EPA receives a NOC, the Successor in Interest must comply with the terms of this Consent Order and will not be required to submit a new PMN to EPA.

(c) Definitions. The following definitions apply to this Successor Liability section of the Consent Order:

(1) "Successor in Interest" means a person outside the Company who has acquired the Company's full interest in the rights to manufacture the PMN substances, including all ownership rights and legal liabilities, through a transfer document signed by the Company, as transferor, and the Successor in Interest, as transferee. The term excludes persons who acquire less than the full interest of the Company in the PMN substances, such as a licensee who has

acquired a limited license to the patent or manufacturing rights associated with the PMN substances. A Successor in Interest must be incorporated, licensed, or doing business in the United States in accordance with 40 C.F.R. § 720.22(a)(3) and 40 C.F.R. § 720.3(z).

(2) "Transfer Document" means the legal instrument(s) used to convey the interests in the PMN substances, including the right to manufacture the PMN substances, from the Company to the Successor in Interest.

(d) Notices.

(1) Notice to Successor in Interest. On or before the effective date of the transfer, the Company must provide to the Successor in Interest, by registered mail, a copy of the Consent Order and the "Notice of Transfer" document which is incorporated by reference as Attachment B to this Consent Order.

(2) Notice to EPA. Within 10 business days of the effective date of the transfer, the Company must submit the fully executed Notice of Transfer document to EPA as a support document for the PMN, using the procedures set out in 40 C.F.R. § 720.40.

(3) Transfer Document. Copies of the Transfer Document must be maintained by the Successor in Interest at its principal place of business, and at all sites where the PMN substances are manufactured. Copies of the Transfer Document must also be made available for inspection pursuant to § 11 of TSCA, must state the effective date of transfer, and must contain provisions

which expressly transfer liability for the PMN substances under the terms of this Consent Order from the Company to the Successor in Interest.

(e) Liability.

(1) The Company will be liable for compliance with the requirements of this Consent Order until the effective date of the transfer described above.

(2) The Successor in Interest will be liable for compliance with the requirements of this Consent Order effective as of the date of transfer.

(3) Nothing in this section may be construed to prohibit the Agency from taking enforcement action against the Company after the effective date of the transfer for actions taken, or omissions made, during the time in which the Company manufactured, processed, used, distributed in commerce, or disposed of the PMN substances pursuant to the terms of this Consent Order.

(f) Obligations to Submit Test Data under Consent Order. If paragraph (d) of the Testing section of this Consent Order requires the Company to submit test data to EPA at a specified production volume ("test trigger"), the aggregate volume of the PMN substances manufactured by the Company up to the date of transfer will count towards the test trigger applicable to the Successor in Interest.

VI. MODIFICATION AND REVOCATION OF CONSENT ORDER

The Consent Order may be modified only via the procedures in this Section. The Company may request in writing at any time, based upon new information on the human health or environmental effects of, or human exposure to or environmental release of, the PMN substances, that EPA modify or revoke substantive provisions of this Consent Order, including, but not limited to, testing requirements, workplace protections, disposal requirements, or discharge limits. The exposures and risks identified by EPA during its review of the PMN substances and the information EPA determined to be necessary to evaluate those exposures and risks are described in the preamble to this Consent Order. However, in determining whether to amend or revoke the substantive provisions of this Consent Order, EPA will consider all relevant information available at the time the Agency makes that determination, including, where appropriate, any reassessment of the test data or other information that supports the findings in this Consent Order, an examination of new test data or other information or analysis, and any other relevant information.

EPA will respond promptly to such requests for modification or revocation of this Order. The request to modify or revoke this Order shall be submitted in writing, be accompanied by the supporting material the PMN submitter considers necessary to provide the basis for a revocation or modification of the Consent Order.

EPA will issue a modification or revocation if EPA determines that the activities described therein are no longer necessary to protect against an unreasonable risk of injury to

health or the environment and will not result in significant or substantial human exposure or substantial environmental release in the absence of data sufficient to permit a reasoned evaluation of the health or environmental effects of the PMN substances.

In addition, the Company may request in writing at any time that EPA make other modifications to the language of this Consent Order. EPA will issue such a modification if EPA determines that the modification is useful, appropriate, and consistent with the structure and intent of this Consent Order as issued.

VII. EFFECT OF CONSENT ORDER

(a) Waiver. By consenting to the entry of this Consent Order, the Company waives its rights to receive service of this Consent Order no later than 45 days before the end of the applicable review period pursuant to § 5(e)(1)(B) of TSCA and to challenge the validity of this Consent Order in any subsequent action. Consenting to the entry of this Consent Order, and agreeing to be bound by its terms, do not constitute an admission by the Company as to the facts or conclusions underlying the Agency's determinations in this proceeding. This waiver does not affect any other rights that the Company may have under TSCA.

(b) Effective Date. This Consent Order shall be effective upon the expiration of the PMN review period after the EPA's receipt of a fully executed copy of the Consent Order. The EPA will notify the Company of its receipt of the fully executed copy of the Consent Order.

_____	_____
Date	Tala R. Henry, Ph.D. Deputy Director for Programs Office of Pollution Prevention and Toxics
_____	_____
Date	Name: Title: Company:

ATTACHMENT A

DEFINITIONS

"Degradant" means any chemical substance that is identified as a degradation product of any of the test substances as a result of the characterization and testing outlined in "Tier 1 – Physicochemical Properties and Fate."

"The Consortium" is a finite group of chemical manufacturers (including importers) that supply photoacid generator (PAG) substances for use in photolithographic applications in semiconductor manufacturing operations, and those entities that acquire and use those substances in semiconductor manufacturing processes. These entities are listed by name in Attachment D.

"Test substance" means any of the following PMN substances:

- Iodonium, bis[4-(1,1-dimethylethylphenyl]-, salt with 7,7-dimethyl-2-oxobicyclo[2.2.1] heptane-1-methanesulfonic acid(1:1) (CAS: 193345-23-2)
- Sulfonium, triphenyl-, salt with 2,2-difluoro-2-sulfoethyl tricyclo[3.3.1.13,7]decane-1-carboxylate (1:1) (CAS: 1048642-06-3)
- Sulfonium, tris[4-(1,1-dimethylethyl)phenyl]-, 1,1,2,2,3,3,4,4,4-nonafluoro-1-butanesulfonate (1:1) (CAS: 241806-75-7)
- Thiophenium, 1-[4-(1,1-dimethylethyl)phenyl]tetrahydro-, salt with 1,1,2,2,3,3,4,4,4-nonafluoro-1- butanesulfonic acid (1:1) (CAS: 900188-13-8)
- Sulfonium, (4-hydroxyphenyl)diphenyl-, salt with trifluoromethanesulfonic acid (1:1) (CAS: 141801-36-7)

The "PAG Category", for purposes of the TSCA New Chemicals program, are typically salts that consist of a sulfonium or iodonium cation designed to interact with ultraviolet (UV) light at the appropriate wavelengths, thus generating a super acid to assist in the development of photoresists, and an anion which may be present to increase stability of the salt or for other performance issues.

ATTACHMENT B

NOTICE OF TRANSFER
OF
TOXIC SUBSTANCES CONTROL ACT
SECTION 5(e) CONSENT ORDER

_____ _____
Company (Transferor) PMN Number

1. Transfer of Manufacture Rights. Effective on _____, the Company did sell or otherwise transfer to _____, ("Successor in Interest") the rights and liabilities associated with manufacture of the above-referenced chemical substance, which was the subject of a premanufacture notice ("PMN") and is governed by a Consent Order issued by the U.S. Environmental Protection Agency ("EPA") under the authority of §5(e) of the Toxic Substances Control Act ("TSCA," 15 U.S.C. §2604(e)).

2. Assumption of Liability. The Successor in Interest hereby certifies that, as of the effective date of transfer, all actions or omissions governed by the applicable Consent Order limiting manufacture, processing, use, distribution in commerce and disposal of the PMN substance, will be the responsibility of the Successor in Interest. Successor in Interest also certifies that it is incorporated, licensed, or doing business in the United States in accordance with 40 C.F.R. § 720.22(a)(3).

3. Confidential Business Information. The Successor in Interest hereby:

___ reasserts,

___ relinquishes, or

___ modifies

all Confidential Business Information ("CBI") claims made by the Company, pursuant to Section 14 of TSCA and 40 C.F.R. pt. 2, for the PMN substance(s). Where "reasserts" or "relinquishes" is indicated, that designation will be deemed to apply to all such claims. Where "modifies" is indicated, such modification will be explained in detail in an attachment to this Notice of Transfer. Information which has been previously disclosed to the public (e.g., a chemical identity that was not claimed as CBI by the original submitter) would not subsequently be eligible for confidential treatment under this Notice of Transfer.

In order to make a confidentiality claim for information submitted to EPA, an authorized official of the Successor in Interest must certify that it is true and accurate that the Successor in Interest has:

(1) Taken reasonable measures to protect the confidentiality of the information;

(2) Determined that the information is not required to be disclosed or otherwise made available to the public under any other Federal law;

(3) A reasonable basis to conclude that the disclosure of the information is likely to cause substantial harm to the competitive position of the Successor in Interest; and

(4) A reasonable basis to believe that the information is not readily discoverable through reverse engineering.

CBI claims for chemical identity must be accompanied by a generic chemical identity, which may be that used for the PMN.

NOTICE OF TRANSFER OF
TOXIC SUBSTANCES CONTROL ACT
SECTION 5(e) CONSENT ORDER

(continued)

_____ _____
Company (Transferor) PMN Number

_____ _____
Signature of Authorized Official Date

_____
Printed Name of Authorized Official

_____
Title of Authorized Official

_____
Successor in Interest

_____ _____
Signature of Authorized Official Date

_____
Printed Name of Authorized Official

_____
Title of Authorized Official

_____
Address

_____
City, State, Zip Code

NOTICE OF TRANSFER OF
TOXIC SUBSTANCES CONTROL ACT
SECTION 5(e) CONSENT ORDER
(continued)

_____
Successor's Technical Contact

_____
Address

_____
City, State, Zip Code

_____
Phone

ATTACHMENT C

Attached PDF titled Semiconductor Photoacid Generator Use Rates and Releases

Commented [34]: The PAG Consortium presented an updated version of this in our recent meeting with Agency personnel and requests that the most recent edition be included. We will supply the most recent edition separately.

ATTACHMENT D

Members of Photoacid Generator Semiconductor Consortium

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